

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

| | | |
|--|---|--------------------------------|
| CITY OF HUNTINGTON, |) | |
| |) | |
| Plaintiff, |) | Civil Action No. 3:17-cv-01362 |
| |) | |
| v. |) | |
| |) | |
| AMERISOURCEBERGEN DRUG CORPORATION, ET AL., |) | |
| |) | |
| Defendants. |) | |
| |) | |
| <hr style="width: 40%; margin-left: 0;"/> | | |
| CABELL COUNTY COMMISSION, |) | Consolidated case: |
| |) | Civil Action No. 3:17-cv-01665 |
| Plaintiff, |) | |
| |) | |
| v. |) | |
| |) | |
| AMERISOURCEBERGEN DRUG CORPORATION, ET AL., |) | |
| |) | |
| Defendants. |) | |
| |) | |
| <hr style="width: 40%; margin-left: 0;"/> | | |

**DEFENDANTS’ OPPOSITION TO PLAINTIFFS’ MOTION TO LIMIT THE
TESTIMONY OF TRICIA WRIGHT, M.D.**

Plaintiffs seek to limit the testimony of defense expert Tricia Wright, M.D. Specifically, they argue that Dr. Wright should not be allowed to offer opinions regarding babies with neonatal abstinence syndrome (NAS) on two grounds: (1) that she is not qualified to offer such opinions because she is an obstetrician-gynecologist and addiction specialist who treats women, but does not treat babies; and (2) that her opinions lack foundation because she purportedly relied only upon “her casual observations of children who pass through her clinic.” Pl. Mot., Dkt No. 1082, at 1. Plaintiffs’ attempt to limit the scope of Dr. Wright’s NAS opinions fails because it incorrectly

characterizes Dr. Wright's qualifications and experience. In her dual roles as an OB-GYN and an addiction medicine specialist, Dr. Wright treats and counsels pregnant women whose children are at risk of experiencing NAS or other post-natal effects of substance exposure; as a result, she is deeply familiar with the disease, its causes, and its impact. This experience is reflected not merely in her day-to-day clinical experience but also in her contributions to the scientific and medical literature, and it is set forth extensively in her expert report and curriculum vitae (CV), attached hereto as Exhibit A. Plaintiffs engaged in only limited questioning during Dr. Wright's deposition that did not elicit full testimony regarding those evidentiary cornerstones for her expert opinions. These cornerstones establish that Dr. Wright fully meets the standards set forth by *Daubert* and Rule 702.

I. LEGAL STANDARD

Expert testimony in the federal courts is governed by Federal Rule of Evidence 702. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II)*, MDL 2502, 892 F.3d 624, 631 (4th Cir. 2018). Rule 702 "permits an expert to testify where the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue, so long as the expert's opinion is based on sufficient facts or data, is the product of reliable principles and methods, and the expert has reliably applied the principles and methods to the facts of the case." *Id.* (quoting Fed. R. Evid. 702) (internal quotations omitted). The Fourth Circuit recognizes that "a witness may be qualified as an expert on the grounds of knowledge, skill, experience, training *or* education. . . . [T]he use of the disjunctive indicates that a witness may be qualified as an expert on any one of the five listed grounds" of Rule 702. *Friendship Heights Assocs. v. Vlastimil Koubek, A.I.A.*, 785 F.2d 1154, 1159 (4th Cir. 1986) (emphasis in original) (internal quotations and citations omitted).

II. ARGUMENT

Plaintiffs' argument hinges on an incorrect presumption: that because Dr. Wright does not personally *treat* infants but instead treats their pregnant mothers, her expertise and her work do not involve knowledge about conditions affecting infants. This is, as set forth in Dr. Wright's report, false. Part and parcel of her care of pregnant women who have substance abuse problems is counseling them about the potential impact of their substance use on their babies. She states:

Throughout the course of my clinical practice, I have diagnosed, treated, *counseled*, and cared for thousands of pregnant and parenting women with substance use disorders, including opioid use disorder. . . . As a matter of course, I have *counseled* women on the effects of opioids on pregnancy, the need for treatment with medication as addiction treatment (MAT), *as well as the incidence, prevention, and treatment of neonatal withdrawal. For many years, my partners and I at the University of Hawaii delivered the babies and cared for their mothers in the hospital after delivery. It is important for the mothers to understand NAS and, if it occurs, for them to play an active role in the support and care of their babies through the withdrawal process.*

Wright Report, Dkt. 1082-1, at 2 (emphasis added). In order to provide proper treatment to her pregnant patients, Dr. Wright is required to be expert in the potential effects of substance abuse on their babies, which includes NAS.

Dr. Wright's expertise in the detection and effects of maternal substance ingestion, including NAS, on children is evidenced by her record of publication in the peer-reviewed medical literature and her educational presentations to other medical professionals. For example, Dr. Wright has published the following articles in the peer-reviewed literature:

- Substance use disorders in pregnancy: clinical, ethical, and research imperatives of the opioid epidemic: a report of a joint workshop of the Society for Maternal-Fetal Medicine, American College of Obstetricians and Gynecologists, and American Society of Addiction Medicine, *Am. J. of Obstetrics and Gynecology*, 2019;221 (1):B5-b28. This report includes a section headed "Fetal and neonatal effects of [Medication Assisted Therapy with opioids]" and discusses the lack of proven long-term effects from exposure to methadone or buprenorphine during pregnancy as well as the need for maternal counseling about NAS by prenatal care providers. *Id.*, Exhibit B, at B17-18.

- Detection of opioids in umbilical cord lysates: an antibody-based rapid screening approach, *Toxicol. Mech. Methods.*, 2019 Jan; 29(1):35-42.
- Screening Pregnant Women and Their Neonates for Illicit Drug Use: Consideration of the Integrated Technical, Medical, Ethical, Legal, and Social Issues, *Frontiers in Pharmacology*, 2018;9(961).
- Sex-Specific Alterations of White Matter Developmental Trajectories in Infants With Prenatal Exposure to Methamphetamine and Tobacco, *JAMA Psychiatry*, 2016; doi: 10.1001/jamapsychiatry.2016.2794.
- Biochemical Screening for in utero Drug Exposure, *Drug metabolism letters*, 2015;9(2):65-71.
- The effects of cocaine and amphetamine use during pregnancy on the newborn: myth versus reality, *J. of Addictive Diseases*, 2011;30(1):1-5.

Wright CV, Exhibit A, at 2-4. She has educated her peers on risks, including NAS, to fetuses and children from maternal substance use disorders, including in the following:

- Maternal/Fetal Risks from Opioid Use Disorders: What You Need to Know, ACOG Update (2017), Volume 43(5).
- NAS is Temporary, FAS is Permanent: Understanding Alcohol Use in Women, Conference Presentation at the American College of Obstetricians and Gynecologists Annual Clinical Meeting, Nashville, TN, May 2019; Stanford University Grand Rounds, Stanford, CA, September 2018.
- SUD Services for Special Populations: Neonatal Abstinence Syndrome, Targeted Learning Opportunity for Center for Medicare and Medicaid Services, March 14, 2016, Webinar.

Wright CV, Exhibit A, at 5, 8-9. And Dr. Wright was the sole editor of a 2018 textbook, *Opioid-Use Disorders in Pregnancy: Management Guidelines for Improving Outcomes*, which included two chapters on newborns, including one specifically on NAS. See *Opioid-Use Disorders in Pregnancy* (2018), Exhibit C, at Table of Contents. Plaintiffs had the opportunity to question Dr. Wright about the information she provides to other doctors in these presentations and publications,

and that questioning included her basis for arriving at her opinions. *See, e.g.*, Wright Deposition, Dkt. 1082-2, at 78:22-79:24.¹

In addition to her particular expertise in the effects of substance use on fetuses, infants, and children, Dr. Wright is well-versed in medical literature relating to newborn and child health. Specifically, she is an editorial board member of the Maternal and Child Health Journal, a journal devoted to publishing peer-reviewed papers that “address [Maternal and Child Health ‘MCH’] practice, policy, and research, exploring such topics as MCH epidemiology, demography, and health status assessment; Innovative MCH service initiatives; Implementation of MCH programs; MCH policy analysis and advocacy and MCH professional development.” Maternal and Child Health Journal, <https://www.springer.com/journal/10995> (last visited Oct. 23, 2020). She is also a peer reviewer for the Journal of Perinatology, the “official publication of the Section on Neonatal-Perinatal Medicine, the American Academy of Pediatrics, and the National Perinatal Association of the United States,” which deals exclusively with topics that “that have a direct relevance to fetal/and or neonatal care and outcomes.” Journal of Perinatology, About the Journal, <https://www.nature.com/jp/about> (last visited Oct. 23, 2020). (Perinatology is the medical

¹ “Q: And can you tell me generally about what your message is or the conclusions you make in that presentation about NAS being temporary?”

A: Yes. So my conclusions are that fetal – or fetal alcohol syndrome is a permanent, lifelong condition caused by alcohol use during pregnancy, and it often coexists with neonatal abstinence syndrome, so that for the addiction medicine providers, I am having them focus and looking for concurrent alcohol use along with opioid use. And for the OB/Gyns that focus – I’m trying to get them to screen for alcohol use during pregnancy, which is much more harmful than opioid use.

Q: And do you cite to any studies for the proposition that NAS is temporary?

A: Yes, there’s very many studies looking at long-term outcomes. We’ve had almost 50 years of experience with methadone. And when they’ve looked at the children and now adults, when you control for other factors, including co-occurring tobacco use, alcohol use, poverty, poor diet, systemic racism, there has been no effects that can be directly linked to the opioids themselves.”

specialty concerned with the care of the mother, fetus, and infant during the perinatal period, the period immediately surrounding birth; neonatology is the medical specialty concerned specifically with newborn infants.) This renders her fully qualified to review the medical literature surrounding NAS issues – which Plaintiffs do not deny is a legitimate methodology. *See* Pl. Mot., Dkt. 1082, at 7-8.

In light of Dr. Wright’s extensive experience with the scientific literature surrounding NAS and the effects of *in utero* substance exposure, Plaintiffs’ argument that Dr. Wright is not qualified to offer NAS opinions because she is not a pediatrician and does not provide medical care to babies improperly expands the gatekeeping role of *Daubert*. *See McCulloch, v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) (noting that requiring an expert to be a specialist in a specific field is “an unwarranted expansion of the gatekeeper role announced in *Daubert*”). “If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent.” *In re Zyprexa Prod. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007); *see also Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 81–82 (2d Cir. 1997) (finding that an expert is qualified when his experience, knowledge, or training relate to a general area even if not to the specific question before the trier of fact). That is the case here.

In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig., 612 F. Supp. 2d 116 (D. Mass. 2009), cited by Plaintiffs, is not to the contrary. In that case, the defense challenged (to no avail) two of plaintiffs’ experts by arguing that they were not qualified in specific disciplines. The court found that the expert psychiatrist was qualified to testify about the mechanism of action of gabapentin even though he was not a practicing pharmacologist per se. *See id.* at 157–58.

Although the physician was a psychiatrist, he also had specialized training and knowledge in psychopharmacology, 28 years of clinical practice experience, had previously served as an expert witness in pharmaceutical litigation, was on the faculty at a university, had authored published articles, and reviewed research from peer-reviewed sources. *Id.* at 157. Likewise, the court found that an expert in pharmacology and toxicology who had worked with pharmaceutical companies to prepare new drug applications for submittal to FDA was also qualified to testify about the drug's mechanism of action and general causation. *Id.* at 158. She "reviewed the same types of records and applied the same analytical methods used by the FDA to evaluate a drug's risks, benefits, safety, and efficacy." *Id.* The court, therefore, determined that she was "amply qualified at least to evaluate the adverse event data and other sources of information regularly used by the FDA and industry professionals." *Id.* Here, Dr. Wright has had training and experience with NAS, many years of clinical experience with mothers and their babies, has published articles and peer-reviewed the articles of others, and has done a thorough review and evaluation of the NAS literature.

Finally, Dr. Wright's opinions are based on adequate foundation under Rule 702. In order to effectively counsel her patients about the potential short-term and long-term consequences of their substance use on their babies, Dr. Wright must be readily familiar with the published literature and clinical guidelines regarding the mother-child dyad and how substance use during pregnancy impacts both mother *and* child. The published literature supporting her NAS opinions are included in the 47 peer-reviewed articles listed in her "Materials Considered and/or Relied Upon" list attached to her expert report. As Dr. Wright confirmed in her report, her opinions are based on her education, training, research, clinical experience, activities in professional organizations, and knowledge of the medical and scientific literature. Wright Report, Dkt. 1082-1, at 3. Dr. Wright

also explained in her deposition that her opinions are “based not only on [her] extensive review of the literature but also from the 13 years that [she] spent taking care of women with substance use disorder.” Wright Deposition, Dkt. 1082-2, at 86:5-14. This analysis more than meets the standard under *Daubert*. See, e.g., *In re Seroquel Prod. Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 WL 3806435 (M.D. Fla. June 23, 2009) (holding that a review of the literature and assessment based on the weight of the evidence was sufficiently reliable foundation and methodology to admit expert’s testimony).

In sum, Dr. Wright’s education, training, experience, peer-reviewed publications, and review of the medical literature in this case demonstrate that she is qualified and has sufficient foundation for her NAS opinions.

III. CONCLUSION

Based on the foregoing arguments and authorities, Defendants respectfully request that the Court deny Plaintiffs’ motion to limit the testimony of Tricia Wright, M.D.

Dated: October 23, 2020

Respectfully submitted,

/s/ Timothy C. Hester

Timothy C. Hester (DC 370707)

Laura Flahive Wu

Andrew P. Stanner

COVINGTON & BURLING LLP

One CityCenter

850 Tenth Street NW

Washington, DC 20001

Tel: (202) 662-5324

thester@cov.com

lflahivewu@cov.com

astanner@cov.com

/s/ Paul W. Schmidt

Paul W. Schmidt

COVINGTON & BURLING LLP

The New York Times Building

620 Eighth Avenue
New York, New York 10018
Tel: (212) 841-1000
pschmidt@cov.com

/s/ Jeffrey M. Wakefield

Jeffrey M. Wakefield (WVSB #3894)
jwakefield@flahertylegal.com
Jason L. Holliday (WVSB #12749)
jholliday@flahertylegal.com
FLAHERTY SENSABAUGH BONASSO PLLC
P.O. Box. 3843
Charleston, WV 25338-3843
Telephone: (304) 345-0200

Counsel for McKesson Corporation

/s/ Gretchen M. Callas

Gretchen M. Callas (WVSB #7136)
JACKSON KELLY PLLC
Post Office Box 553
Charleston, WV 25322
Tel: (304) 340-1000
Fax: (304) 340-1050
gcallas@jacksonkelly.com

/s/ Robert A. Nicholas

Robert A. Nicholas
Shannon E. McClure
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420
rnicholas@reedsmith.com
smcclure@reedsmith.com

Counsel for AmerisourceBergen Drug Corporation

/s/ Steven R. Ruby

Michael W. Carey (WVSB No. 635)
Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
Raymond S. Franks II (WVSB No. 6523)

CAREY DOUGLAS KESSLER & RUBY PLLC
901 Chase Tower, 707 Virginia Street, East
P.O. Box 913
Charleston, WV 25323
Telephone: (304) 345-1234
Facsimile: (304) 342-1105
mwcarey@csdlawfirm.com
sruby@cdkrlaw.com
drpogue@cdkrlaw.com
rsfranks@cdkrlaw.com

/s/ Enu Mainigi
Enu Mainigi
F. Lane Heard III
Ashley W. Hardin
Jennifer G. Wicht
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
Tel: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com
lheard@wc.com
ahardin@wc.com
jwicht@wc.com

Counsel for Cardinal Health, Inc.

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 23rd day of October, 2020 the foregoing *Defendants' Opposition to Plaintiffs' Motion to Limit the Testimony of Tricia Wright, M.D.* was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Timothy C. Hester
Timothy C. Hester (DC 370707)